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EXAMINER

THANGAVELU, KANDASAMY

| ART UNIT | PAPER NUMBER |
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2123

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,982

Applicant(s)

ST. VILLE, JAMES A.

Examiner

Kandasamy Thangavelu

Art Unit

2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/23/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Introduction

1. Claims 1-42 of the application are pending.

Domestic Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) based on a provisional application 60/149,896 dated August 23, 1999 is acknowledged.

Information Disclosure Statement

3. Acknowledgment is made of the information disclosure statements filed on January 16, 2001 together with copies of the papers and patents. The papers and patents have been considered in reviewing the claims.

Drawings

4. Figures 1, 2A, 2B, 3A, 3B, 4, 5A, 5B, 6 and 8 appear in **St. Ville (VI)** (U.S. Patent 5,796,617) as Figures 3, 4A, 4B, 5A, 5B, 6, 7A, 7B, 8 and 10. So all these figures in the application shall be labeled as Prior Art.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4-9 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following corresponding claims of U.S. Patent No. 5,594,651. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Applicant has not disclosed if and how specifying that the material properties of the finite elements have a particular symmetry affects the method of manufacturing.

The elements of Claim 1 correspond to the elements of Claim 1 of '651 patent.

The elements of Claim 4 correspond to the elements of Claim 2 of '651 patent.

The elements of Claim 5 correspond to the elements of Claim 3 of '651 patent.

The elements of Claim 6 correspond to the elements of Claim 4 of '651 patent.

The elements of Claim 7 correspond to the elements of Claim 5 of '651 patent.

The elements of Claim 8 correspond to the elements of Claim 6 of '651 patent.

The elements of Claim 9 correspond to the elements of Claim 7 of '651 patent.

The elements of Claim 22 correspond to the elements of Claim 17 of '651 patent.

7. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 6,263,252. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Applicant has not disclosed if and how specifying that the material properties of the finite elements have a particular symmetry affects the method of manufacturing. All the elements of Claim 21 correspond to the elements of Claim 15 of '252 patent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 2, 4-10, 21-27 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077).

10.1 **VI** teaches a method and apparatus for manufacturing a prosthesis having optimized response characteristics. Specifically, as per Claim 1, **VI** teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied. (Col 4, Lines 46-48 and Col 6, Lines 47-56). **VI** teaches that the method includes generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements. (Col 4, Lines 49-52). **VI** teaches that the method includes specifying values for the field { f } and potential { x } relative to the finite elements. (Col 4, Lines 53-54). **VI** teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry. (Col 4, Lines 54-55).

VI teaches that the method includes extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model. (Col 4, Lines 56-58). **VI** teaches that the method includes comparing the extracted material

property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials. (Col 4, Lines 58-62). **VI** teaches that the method includes determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients. (Col 4, Lines 62-64). **VI** teaches that the method includes controlling the manufacturing equipment in accordance with the determined manufacturing parameters to thereby manufacture the object. (Col 4, Lines 64-65).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry. (Col 1, Lines 65-67 and Col 5, Lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would describe the manufacturing method applicable to the composite material having such symmetrical properties.

10.2 As per Claim 2, **VI** and **WU** teach the method of Claim 1. **VI** does not expressly teach that the material properties of the finite elements are specified to be isotropic. **WU** teaches that the material properties of the finite elements are specified to be isotropic. (Col 5, Lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU**, as that would describe the manufacturing method applicable to the composite material having such isotropic properties.

10.3 As per Claim 4, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the step of generating a computerized mathematical model of the object includes determining the smallest volume increment that can be manufactured using the composite manufacturing equipment. (Col 13, Lines 6-13 and Col 13, Lines 26-28).

10.4 As per Claim 5, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is a mechanical force field and the potential { x } is a displacement. (Col 7, Line 57 to Col 8, Line 4).

10.5 As per Claim 6, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is an electric current field and the potential { x } is a voltage. (Col 7, Line 57 to Col 8, Line 4).

10.6 As per Claim 7, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is a magnetic field and the potential { x } is a magnetic vector potential. (Col 7, Line 57 to Col 8, Line 4).

10.7 As per Claim 8, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is a thermal flux field and the potential { x } is a temperature. (Col 7, Line 57 to Col 8, Line 4).

10.8 As per Claim 9, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field $\{f\}$ is a fluid velocity field and the potential $\{x\}$ is a fluid potential. (Col 7, Line 57 to Col 8, Line 4).

10.9 As per Claim 10, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the step of controlling the manufacturing equipment comprises controlling a composite manufacturing equipment for manufacturing a composite material. (Col 12, Lines 18-23 and Col 12, Lines 28-34).

10.10 As per Claim 21, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force $\{f\}$ and displacement $\{x\}$ are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 27-29 and Col 8, Lines 43-48).

10.11 As per Claim 22, **VI** and **WU** teach the method of Claim 1. **VI** teaches an article of manufacture made in accordance with the method of claim 1. (Col 6, Lines 61-65). **VI** teaches that the article is selected from the group consisting of an automobile part, an aircraft part, a prosthetic implant, a golf club shaft, a tennis racket, a bicycle frame, and a fishing pole. (Col 6, Lines 61-65). **VI** teaches that different portions of the article have different material properties corresponding to the matched extracted material property coefficients for known materials. (Col 4, Lines 49-62).

10.12 As per Claim 23, **VI** and **WU** teach the method of Claim 1. **VI** teaches a prosthetic implant manufactured in accordance with the method of claim 1. (Col 6, Lines 61-65).

10.13 As per Claim 24, **VI** and **WU** teach the method of Claim 1. **VI** teaches a golf club manufactured in accordance with the method of claim 1. (Col 6, Lines 61-65).

10.14 As per Claim 25, **VI** teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential $\{x\}$ that is generated in response to a field $\{f\}$ applied. (Col 14, Lines 49-53 and Col 6, Lines 47-56). **VI** teaches that the method includes generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements. (Col 4, Lines 49-52). **VI** teaches that the method includes specifying values for the field $\{f\}$ and potential $\{x\}$ relative to the finite elements. (Col 4, Lines 53-54). **VI** teaches that the method includes calculating a material property matrix $[k]$ based on the relationship $\{f\}=[k]\{x\}$ and the specified symmetry. (Col 4, Lines 54-55).

VI teaches that the method includes extracting material property coefficients from the material property matrix $[k]$ for each finite element in the computerized mathematical model. (Col 4, Lines 56-58). **VI** teaches that the method includes comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials. (Col 4, Lines 58-62). **VI** teaches that the method includes determining manufacturing parameters for

controlling manufacturing equipment based on the matched material property coefficients. (Col 4, Lines 62-64). **VI** teaches that the method includes generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing parameters. (Col 14, Lines 49-53).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry. (Col 1, Lines 65-67 and Col 5, Lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would describe the manufacturing method applicable to the composite material having such symmetrical properties.

10.15 As per Claim 26, **VI** and **WU** teach the method of Claim 25. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force $\{f\}$ and displacement $\{x\}$ are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 27-29 and Col 8, Lines 43-48).

10.16 As per Claim 27, **VI** and **WU** teach the method of Claim 25. **VI** also teaches that the step of generating machine control instructions comprises generating machine control instructions for

controlling composite manufacturing equipment for manufacturing a composite material. (Col 14, Lines 49-53 and Col 12, Lines 28-34).

10.17 As per Claim 38, **VI** and **WU** teach the method of Claim 25. **VI** also teaches a computer system programmed to perform the method of claim 25. (Col 13, Line 58 to Col 14, 63 and Col 14, Lines 64-66).

10.18 As per Claim 39, **VI** and **WU** teach the method of Claim 25. **VI** also teaches a control system programmed with machine control instructions for controlling composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Col 12, Lines 28-30 and Col 12, Lines 44-47).

10.19 As per Claim 40, **VI** and **WU** teach the method of Claim 25. **VI** also teaches composite manufacturing equipment comprising a control system programmed with machine control instructions for controlling the composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Fig. 10; Col 12, Lines 44-47 and Col 15, Lines 33-47).

10.20 As per Claim 41, **VI** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response. (Col 14, Lines 49-53 and Col 6, Lines 47-56). **VI** teaches that the method includes generating a computerized mathematical model of the object

by discretizing a geometric model of the object into a plurality of finite elements. (Col 4, Lines 49-52). **VI** teaches that the method includes specifying values of the field $\{ f \}$ and potential $\{ x \}$ relative to the finite elements. (Col 4, Lines 53-54). **VI** teaches that the method includes calculating a material property matrix $[k]$ based on the relationship $\{ f \} = [k] \{ x \}$ and the specified symmetry. (Col 4, Lines 54-55).

VI teaches that the material property matrix $[k]$ comprises a plurality of values each corresponding to one or more material property coefficients. (Col 4, Lines 56-62). **VI** teaches that the method includes comparing each of the plurality of values in the material property matrix $[k]$ to known material properties. (Col 4, Lines 58-62). **VI** teaches that the method includes responsive to a match, selecting a corresponding manufacturing process parameter, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material. (Col 4, Lines 62-64 and Col 12, Lines 28-30). **VI** teaches that the method includes controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object. (Col 14, Lines 49-53).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry. (Col 1, Lines 65-67 and Col 5, Lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry,

as that would describe the manufacturing method applicable to the composite material having such symmetrical properties.

10.21 As per Claim 42, **VI** and **WU** teach the method of Claim 41. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force {f} and displacement {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 27-29 and Col 8, Lines 43-48).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), further in view of **Legere (LE)** (U.S. Patent 6,087,571).

11.1 As per Claim 3, **VI** and **WU** teach the method of Claim 1. **VI** does not expressly teach that the material properties of the finite elements are specified to be transversely isotropic. **LE** teaches that the material properties of the finite elements are specified to be transversely isotropic. (Col 6, Lines 55-65). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **LE** that specifies that the material properties of the finite elements be transversely isotropic, since that would describe the manufacturing method for materials having transversely isotropic material properties.

12. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), further in view of **Castanie et al (CA)** (U.S. Patent 6,290,889).

12.1 As per Claim 11, **VI** and **WU** teach the method of Claim 10. **VI** does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **CA** teaches the composite material comprises structural fibers laminated in a matrix. (Col 1, Lines 9-11 and 14-21). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **CA** that specifies that the composite material comprises structural fibers laminated in a matrix, since that would describe the manufacturing method for materials comprising structural fibers laminated in a matrix.

12.2 As per Claim 28, **VI** and **WU** teach the method of Claim 27. **VI** does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **CA** teaches the composite material comprises structural fibers laminated in a matrix. (Col 1, Lines 9-11 and 14-21). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **CA** that specifies that the composite material comprises structural fibers laminated in a matrix, since that would describe the manufacturing method for materials comprising structural fibers laminated in a matrix.

13. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and

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Castanie et al. (CA) (U.S. Patent 6,290,889), further in view of **Rauscher et al. (RA)** (U.S. Patent 4,889,526).

13.1 As per Claim 12, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes biologic material. **RA** teaches that the matrix includes biologic material. (Col 37, Lines 61-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **RA** that specifies that the matrix included biologic material, since that would describe the manufacturing method for artificial parts with biologic material which are excitable by magnetic or electric current field.

13.2 As per Claim 29, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes biologic material. **RA** teaches that the matrix includes biologic material. (Col 37, Lines 61-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **RA** that specifies that the matrix included biologic material, since that would describe the manufacturing method for artificial parts with biologic material which are excitable by magnetic or electric current field.

14. Claims 13 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Johnson et al. (JO)** (U.S. Patent 6,296,667).

14.1 As per Claim 13, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes bone. **JO** teaches that the matrix includes bone. (Col 6, Lines 13-25). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **JO** that specifies that the matrix included bone, since that would describe the manufacturing method for bone substitute materials that could be used in producing artificial limbs and other human body parts.

14.2 As per Claim 30, **VI**, **WU** and **CA** teach the method of Claim 281. **VI** does not expressly teach that the matrix includes bone. **JO** teaches that the matrix includes bone. (Col 6, Lines 13-25). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **JO** that specifies that the matrix included bone, since that would describe the manufacturing method for bone substitute materials that could be used in producing artificial limbs and other human body parts.

15. Claims 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Wack (WAC)** (U.S. Patent 6,126,659).

15.1 As per Claim 14, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes crushed bone. **WAC** teaches that the matrix includes crushed bone. (Col 1, Lines 21-22 and 29-37). It would have been obvious to one of ordinary skill in the

art at the time of Applicant's invention to modify the method of **VI** with method of **WAC** that specifies that the matrix included crushed bone, since that would describe the manufacturing method for materials including crushed bone which are used in artificial limbs and in prosthesis.

15.2 As per Claim 31, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes crushed bone. **WAC** teaches that the matrix includes crushed bone. (Col 1, Lines 21-22 and 29-37). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **WAC** that specifies that the matrix included crushed bone, since that would describe the manufacturing method for materials including crushed bone which are used in artificial limbs and in prosthesis.

16. Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Warren, Jr. (WA)** (U.S. Patent 6,348,042).

16.1 As per Claim 15, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes co-factors. **WA** teaches that the matrix includes co-factors. (abstract). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **WA** that specifies that the matrix included co-factors, since that would describe the manufacturing method for materials including co-factors which are useful to excite activation of the enzymes.

16.2 As per Claim 32, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes co-factors. **WA** teaches that the matrix includes co-factors. (abstract). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **WA** that specifies that the matrix included co-factors, since that would describe the manufacturing method for materials including co-factors which are useful to excite activation of the enzymes.

17. Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Tadros et al. (TA)** (U.S. Patent 6,121,033).

17.1 As per Claim 16, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes biological cells. **TA** teaches that the matrix includes biological cells. (Col 14, Lines 39-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **TA** that specifies that the matrix included biological cells, since that would describe the manufacturing method for materials including biological cells which are completely degradable into biomass without having toxic effect on the microbes.

17.2 As per Claim 33, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes biological cells. **TA** teaches that the matrix includes biological cells. (Col 14, Lines 39-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **TA** that specifies that the matrix included biological cells, since that would describe the manufacturing method for materials including biological cells which are completely degradable into biomass without having toxic effect on the microbes.

18. Claims 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Slaikou (SL)** (U.S. Patent 6,231,590).

18.1 As per Claim 17, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes bio-active materials. **SL** teaches that the matrix includes bio-active materials. (Col 7, Lines 15-21). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **SL** that specifies that the matrix included bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which are useful to reducing friction, providing a therapeutic for local or blood delivery etc.

18.2 As per Claim 34, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes bio-active materials. **SL** teaches that the matrix includes bio-active materials. (Col 7, Lines 15-21). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **SL** that specifies that the matrix included bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which are useful to reducing friction, providing a therapeutic for local or blood delivery etc.

19. Claims 18 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Hermann (HE)** (U.S. Patent 5,098,621).

19.1 As per Claim 18, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes medications. **HE** teaches that the matrix includes medications. (Col 9, Lines 49-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **HE** that specifies that the matrix included medications, since that would describe the manufacturing method for materials including medications which are useful for dressings.

19.2 As per Claim 35, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes medications. **HE** teaches that the matrix includes medications.

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(Col 9, Lines 49-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **HE** that specifies that the matrix included medications, since that would describe the manufacturing method for materials including medications which are useful for dressings.

20. Claims 19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Phipps et al. (PH)** (U.S. Patent 6,289,242).

20.1 As per Claim 19, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes antibiotics. **PH** teaches that the matrix includes antibiotics. (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **PH** that specifies that the matrix included antibiotics, since that would describe the manufacturing method for materials including antibiotics which could be introduced into the host for use as anti-infectives.

20.2 As per Claim 36, **VI**, **WU** and **CA** teach the method of Claim 28. **VI** does not expressly teach that the matrix includes antibiotics. **PH** teaches that the matrix includes antibiotics. (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **PH** that specifies that the

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matrix included antibiotics, since that would describe the manufacturing method for materials including antibiotics which could be introduced into the host for use as anti-infectives.

21. Claims 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,796,617) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Mavity et al. (MA)** (U.S. Patent 6,248,057).

21.1 As per Claim 20, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes radioactive materials. **MA** teaches that the matrix includes radioactive materials. (Col 2, Lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **MA** that specifies that the matrix included radioactive materials, since that would describe the manufacturing method for materials including radioactive materials which could be introduced into the host for controlled release of radioactive materials over time.

21.2 As per Claim 37, **VI**, **WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes radioactive materials. **MA** teaches that the matrix includes radioactive materials. (Col 2, Lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **MA** that specifies that the matrix included radioactive materials, since that would describe the

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manufacturing method for materials including radioactive materials which could be introduced into the host for controlled release of radioactive materials over time.

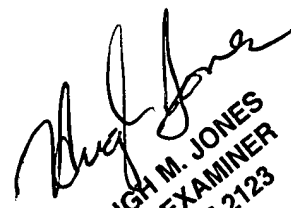
Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7329.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
April 10, 2002


DR. HUGH M. JONES
PATENT EXAMINER
ART UNIT 2123